Exhibit H

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Confirmation No.: 9687

Luigi Giusto SPAGNOLI et al. Group Art Unit: 1643

Application No.: 10/590,479 Examiner: Karen A. CANELLA

Filed: July 20, 2007 Attorney Docket No.: 026073-00007

For: ANTI-CLUSTERIN OLIGOCLONAL ANTIBODIES FOR DIAGNOSIS AND PREDICTION OF THE AGGRESSIVENESS OF TUMOURS, DIAGNOSTIC METHOD AND RELATED KITS

DECLARATION UNDER 37 C.F.R § 1.132 OF LUIGI G. SPAGNOLI

I, Luigi G. Spagnoli, hereby declare and affirm that:

1. My curriculum vitae, including a list of my publications and credentials, is attached as Exhibit A.

2. I am a co-inventor of U.S. Patent Application No. 10/590,479.

3. I have reviewed the disclosure of U.S. Patent Application No. 10/590,479, the currently-pending claims, and the Office Action mailed on December 15, 2008 in this application.

4. I understand that the Office Action has taken the position that currently-pending claims 1, 5-10, 15, and 19-21 are anticipated by Lakins (*J. Biol. Chem.*, 273:27887-27895 (1998)), and that claims 7-9 are obvious in view of Lakins and Kerr (*Immunochemistry LabFax*, pages 118, 128-129, and 158 (1994)).

5. I have been asked to provide my expert opinion regarding the unexpected results obtained as a result of the presently-claimed invention set forth in claims 1, 5-10, 15, and 19-21, which are not exhibited by the cited art.

6. Independent claim 1 relates to oligoclonal antibodies that are able to recognize and bind the antigenic epitope of at least one glycosylated cytoplasmic or non glycosylated nuclear isoform of human clusterin in a selective and specific way, wherein the antigenic epitope of the non glycosylated nuclear isoform is selected from the group of amino acid sequences consisting of QFNWVSRLANLTQGEDQK (SEQ ID No 1), and non glycosylated TKLKELPGVCNETMMALWEE (SEQ ID No 2), and wherein the antigenic epitope of the glycosylated cytoplasmic isoform is selected from the group of amino acid sequences consisting of TKLKELPGVCNETMMALWEE (SEQ ID No 2) glycosylated at its N residue, TNEERKTLLSNLEEAK (SEQ ID No 3), and METVAEKALQEYRKK (SEQ ID No 4), and wherein said epitope is immunogenic.

7. Claims 5-10, 15, and 19-21 each depend directly or indirectly from independent claim 1.

8. Tests were conducted using sandwich ELISA to assess the sensitivity and specificity of various antibodies against secreted clusterin (CLU), including antibodies against human clusterin (anti-SEQ ID NOS: 2-4), and an antibody against the rat clusterin-derived peptide NGDRIDSLLESDRQQSQ (designated anti-SEQ ID NO: 5). The antibodies were generated in rabbits, and were harvested after the fourth immunization booster.

9. Sandwich ELISA was performed by coating plates with anti-Clu-α/β (H-330, sc-8354, Santa Cruz Biotechnologies) and adding serum from healthy human controls and cancer patients. The serum CLU bound by the antibodies raised against secreted human CLU (anti-SEQ ID NOS: 2-4) and the antibody raised against glycosylated rat CLU (anti-SEQ ID NO: 5) was detected. Representative data are shown in Figure 1. All experiments were performed in triplicate.

10. The values shown in Figure 1 are for means ± standard deviations (error bars). The oligoclonal antibodies of the present invention (anti-SEQ ID NOS: 2-4) display higher sensitivity and specificity for detecting secreted clusterin in human serum than the antibody raised against SEQ ID NO: 5. The antibody raised against SEQ ID NO: 5 could not be used to discriminate cancer patients from healthy controls, because the clusterin determination in healthy controls and cancer patients overlapped, when the standard deviations were taken into account.

11. Based on the results of the testing set forth above, I believe that a person skilled in the art, having the disclosures of Lakins and Kerr before him, would not be able to combine their disclosures to arrive at the presently-claimed invention set forth in claims 1, 5-10, 15, and 19-21. Further, I believe that a person skilled in the art, having the disclosures of Lakins and Kerr before him, would consider the level of sensitivity and specificity achieved the oligoclonal antibodies of the presently-claimed invention unexpectedly high.

All statements made herein of my own knowledge are true; all statements made herein on information and belief are believed to be true; and I acknowledge that any willful false statements and the like made herein are punishable by fine or imprisonment, or both under 18 U.S.C. §1001 and may jeopardize the validity of the application or any patent issuing therefrom.

NAME OF DECLARANT

4/7/2009
Date

Exhibits: A – Curriculum Vitae of PROF. LUIGI GIUSTO SPAGNOLO
B – Figure 1

Exhibit A

PROF. LUIGI GIUSTO SPAGNOLI
CURRICULUM VITAE

Name: **Luigi Giusto Spagnoli**
Full Professor and Director of Anatomic Pathology
University of Rome "Tor Vergata"

Date and place of Birth: June 4, 1942, Nerola (Rome)

Education:

1966:	Doctor of Medicine, University of Rome "La Sapienza"
1968:	Specialist in Oncology, University of Rome "La Sapienza"
1969:	Specialist in General Pathology, University of Rome "La Sapienza"
1974:	Specialist in Anatomic Pathology, University of Rome "La Sapienza"

Brief Chronology of Employment:

1966-1973:	Resident, Department of Pathology, University of Rome "La Sapienza"
1973-1983:	Medical Assistant, Department of Pathology, University of Rome "La Sapienza"
1976-1983:	Professor in charge of Anatomic Pathology, University of Rome "La Sapienza"
1983:	Associate Professor of Anatomic Pathology, University of Rome "Tor Vergata"
1984-1996:	Director of Post-graduate School of Pathology and Teacher in other Post-graduate Schools, University of Rome "Tor Vergata"
1985-date:	Full Professsor of Anatomic Pathology, University of Rome "Tor Vergata"
1985-1992:	Director of the Department of Surgery, University of Rome "Tor Vergata"
1987-2001:	Chief of Surgical Pathology Service, S.Eugenio Hospital, Rome
1997-date:	Director of the Department of Biopathology and Image Diagnostics, University of Rome "Tor Vergata"
1999-date:	Coordinator of the Research-Doctorate "Advanced Technologies in Biomedicine" University of Rome "Tor Vergata"
2002-date:	Chief of Surgical Pathology, Policlinico Università Tor Vergata, Rome

Professional appointments:

1984 - 1987:	Member of the Committee for scientific research, of Public Education Ministry
1988 - 1991:	Member of the Committee for Biotechnology and Bioinstrumentations of National Council of Research
1999-2000:	Member of Guarantee Committee of COFIN, MURST
2001-2005:	Head of IFO (Istituti Fisioterapici Ospitalieri)
2004-2005:	Member of the Working Group for Biobanks Certification, National Committee for Biosafety and Biotechnologies, Presidency of Italian Council of Ministers

2005-date: -Head the scientific association "Alleanza contro il Cancro"
2004-date: Member of Scientific Committee of ENEA

Research Interests:

Atherosclerosis and vascular pathology:
a) role of carotid thrombosis in the pathogenesis of cerebrovascular syndromes; b) correlation between the morphological aspects of human fibroatheromasic plaque and the various risk factors; c) role of inflammatory cells in the development of human and experimental atherosclerotic plaque; d) study of inflammatory, metabolic and genetic markers of atherosclerotic plaque vulnerability; e) role of chlamydia pneumoniae in the pathogenesis of acute coronary syndromes; f) role of oxidative stress and oxidated lipoproteins in the progression of human atherosclerotic plaque; g) age-related morphological and morphometrical changes of cellular and interstitial tissue of arterial wall; h) role of metalloproteinases in the pathogenesis of aneurysms of abdominal aorta, of atherosclerosis and restenosis; i) role of myocardial inflammation as pathogenetic factor of coronary syndromes; l) the effect of treatment with calcium antagonist drugs on some cellular markers of hypertension in the aorta of spontaneously hypertensive rats.

Clinical and experimental oncology:
Breast cancer : prognostic factors; Thyroid tumour: latency, cell-C hyperplasy; Non-Hodgkin lymphoma: prognosis factors; Bladder cancer: prognosis factors.
Studies on new prognostic and diagnostic markers of tumour progression and therapeutic success: Expression and activity of new caretaker genes involved in the maintenance of genomic stability and DNA repair.
In vitro and *in vivo* studies in primary and metastatic colorectal cancer:
-New prognostic and predictive factors for colon carcinoma, clinical and molecular studies: new markers of aggressiveness of the tumors in situ and in serum.
Role of Clusterin in cancer
- Role of miRNA in the colon carcinoma progression
-New metabolic target validation involved in tumor progression

Histopathology applied to pharmacotoxicology:
1976 – date: Toxicologic histopathology consultant to Sigma-Tau pharmaceutical company

Present Address:

Cattedra di Anatomia ed Istologia Patologica,
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PROF. LUIGI GIUSTO SPAGNOLI: BIBLIOGRAPHY (1967-2008)

Total IF = 504,615

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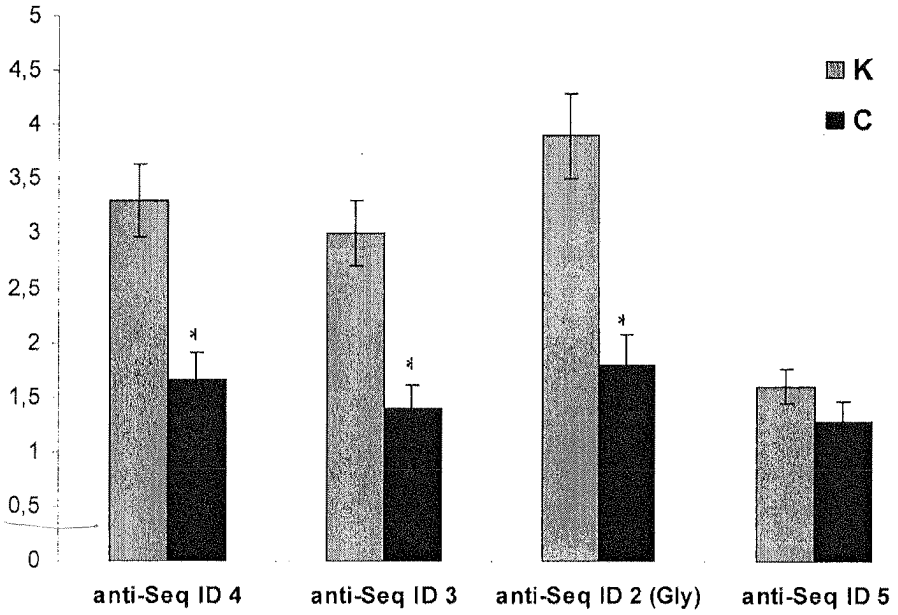
Exhibit B

Figure 1. Sensitivity and specificity of antibodies against secreted CLU (anti-SEQ ID n.2, n.3, n.4) and anti-SEQ ID n.5 (see **D1** document) tested by sandwich ELISA.



Sandwich ELISA was performed coating the plate with anti-Clu-α/β (H-330, sc-8354, Santa Cruz Biotechnologies) and detecting the protein with antibodies raised against secreted CLU **(anti-SEQ ID n.2, n.3, n.4)** or anti-rat Clu (**SEQ ID n.5**) rabbit antibodies. All experiments were performed in triplicate. Representative data are shown. Values are means ± standard deviations (error bars). The invented oligoclonal antibodies (Seq. ID n.2, 3 and 4) display higher sensitivity and specificity, compared to antibody raised against Seq. ID n.5 in detecting secreted Clusterin. * Student's T-test, K vs C: $p \leq 0.05$. K= cancer patients) C= healthy controls.

SEQ ID 5 (document D1) could be not be used to discriminate cancer from healthy patients because the clusterin determination in healthy and cancer patients displays overlapped error bars ($p \geq 0.05$).